

Appln. No. 09/716,356  
Amd. dated March 2, 2005  
Reply to Office Action of September 9, 2004

**REMARKS**

The Office Action has been carefully reviewed. Claims 1, 2 and 4-9 are allowed. Claims 18-52 also presently appear in this application and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

Claims 18-52 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. This rejection is obviated by the amendment to claims 18 and 19 in which the examiner's helpful suggestion has been adopted.

Claims 18, 20, and 21-52 have been rejected under 35 U.S.C. §112, first paragraph, because the examiner states that the specification, while being enabling for a composition comprising SEQ ID NO:6, or for derivatives thereof varying from SEQ ID NO:6 by one amino acid residue, does not reasonably provide enablement for a composition comprising any homologue of the sequence that maintains the biological activities and other characteristics required by claim 18. The examiner states that applicant's three arguments are not persuasive. This rejection is respectfully traversed.

It is noted that the examiner considers that subpart (6) of claim 18 does not add any further guidance as to the

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structure of the claimed homologues. Applicants have now amended subpart (6) of claim 18 to read as follows:

(6) assay  
being detected with a monoclonal antibody  
which binds to the interferon- $\gamma$  inducing  
polypeptide having an amino acid sequence  
of SEQ ID NO:6.

Amended claim 18 provides good guidance for a skilled person to easily understand and obtain the polypeptides as defined in claim 18. That is to say, a skilled person would easily be able to prepare polypeptides having a physicochemical property as recited in subpart (1) of claim 18 with recombinant DNA techniques, and to screen the polypeptides in accordance with the physiochemical property as recited in amended subpart (6) to obtain a relatively small number of polypeptides, and then to further screen the thus obtained relatively small number of polypeptides with respect to the physicochemical properties as recited in subparts (2) to (4) of claim 18 to finally obtain the polypeptides as defined in claim 18. Since these steps are easily understood by one of skill in the art, it is believed that the specification reasonably provides enablement for a composition comprising any homologue of SEQ ID NO:6.

The examiner states that the applicant's third argument is not persuasive because the reference *Journal of Immunological Methods*, Vol. 217 (1998), pages 97-102, teaches that the

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production of human IFN- $\gamma$  is induced when murine IL-18 is applied not to human cells but to modified cells derived from human. The examiner asserts that IFN- $\gamma$  would not be induced in unmodified cells derived from human. The examiner's attention however is invited to the following disclosure on page 99, right column, fourth line from the bottom to page 100, left column, second line of this reference:

The binding of MuIL-18 to KG-1 cells was also detected, but the specific binding was only detectable and it was not possible to calculate the number of sites and the Kd value.

In addition, Table 1 at page 100, left column of this reference shows that unmodified cells derived from human, i.e., KG-1 cells, have MuIL-18 sites even if the number of sites is not as large compared with that in modified KG-1 cells.

In the above reference, modification of KG-1 cells was conducted to increase the number of MuIL-18 binding sites in the cells so as to increase the production of IFN- $\gamma$  induced by MuIL-18. In this regards, it is understood that the production of IFN- $\gamma$  is proportional to the number of MuIL-18 binding sites. Accordingly, the reference discloses that IFN- $\gamma$  is indeed induced even when MuIL-18 is applied to unmodified KG-1 cells, i.e., human cells.

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Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 18, 20, and 21-52 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed.

It would have been easy for a skilled person to understand and obtain the homologues as defined in claim 18 in accordance with the disclosures from page 9, line 5 to page 10, line 9; from page 10, line 10 to page 19, line 12; in Examples 1 to 15; and the state of the art at the time the application was filed. The disclosures in the specification are considered to be substantial Examples of the homologues. Furthermore, it would have be easy for a skilled person to obtain the homologues in accordance with the screening mentioned above.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

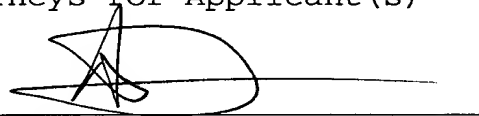
In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their

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allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,  
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By

A handwritten signature in black ink, appearing to be 'Allen C. Yun', written over a horizontal line.

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